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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/802,000

03/16/2004

Thomas Nadackal Thomas

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2824

21901 7590 11/16/2012

Smith & Hopen, P.A.
Attn: General Patent Matters
180 Pine Avenue North
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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT

PAPER NUMBER

1629

NOTIFICATION DATE

DELIVERY MODE

11/16/2012

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/802,000	Applicant(s) THOMAS, THOMAS NADACKAL	
	Examiner PHYLLIS G. SPIVACK	Art Unit 1629	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2012.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-6,8-16 and 18-34 is/are pending in the application.
- 5a) Of the above claim(s) 6,8-16,18,19 and 21-34 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-5 and 20 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/8/12
- 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

An Amendment filed July 6, 2012 is acknowledged. Claim 17 is canceled. Claims 1-6, 8-16 and 18-34 are pending. Claims 6, 8-16, 18, 19 and 21-34 remain withdrawn from consideration, 37 CFR 1.142(b), as drawn to non-elected inventions. Claims 1-5 and 20 remain under consideration. In response to an Election of species Requirement, on August 15, 2011, Applicant elected aspirin as the anti-inflammatory drug. Applicant previously elected the MAO inhibitors deprenyl and propargylamine.

An Information Disclosure Statement filed March 8, 2012 is acknowledged and has been considered.

An objection and rejections set forth in the last Office Action that are not herein reiterated are withdrawn. The following objection and rejections represent the only objection and rejections presently applied to the instant claims.

The disclosure is objected to for the following informality:

Claim 20 is dependent from canceled claim 17.

Appropriate correction is required.

Claims 1-5 and 20 were rejected under 35 U.S.C. 112, first paragraph, in the last Office Action, as failing to comply with the written description requirement. It was asserted there is insufficient written description for preventing or reversing aspirin-induced intestinal lesions following the administration of a MAO inhibitor.

Applicant argues pretreatment with l-deprenyl provided protection against NSAID-induced gastric lesions. Applicant states the NSAID attached to the MAO inhibitor also attenuated the gastric toxicity of NSAIDS, and the gastric lesions were also reversed by daily administration of l-deprenyl for 7 days.

While adequate description is provided for reducing aspirin-induced gastric lesions following the administration of l-deprenyl or propargylamine, page 25, there is no description directly relating to pretreatment that is supported by Table 3. Table 3 does not indicate there was any pretreatment of a MAO inhibitor. Table 3 merely shows a relative reduction of gastric lesions following aspirin ingestion when l-deprenyl is administered independently of aspirin, when aspirin is linked to propargylamine and when aspirin and l-deprenyl are administered for 7 days. Applicant has failed to provide a description drawn to a regimen to follow to reverse or to prevent ulceration following aspirin ingestion. No dosing regimens are described relating to dosing the claimed chemically linked, or “modified” aspirin-deprenyl, or, to independently dosing aspirin and propargylamine. Table 3 does not support a pretreatment or prevention regimen.

As such, claims 1-5 and 20 remain rejected under 35 U.S.C. 112, first paragraph, because the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The knowledge and level of skill in the art would not permit one skilled in the art to

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immediately envisage the claimed method. Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.

The following is a quotation of 35 U.S.C. 112(a):

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), first paragraph:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 is rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for pre-AIA the inventor, at the time the application was filed, had possession of the claimed invention.

The amendment to claim 20 introduces new matter. Applicant has failed to provide support in the specification for such an amendment. See *In re Rasmussen*, 211 USPQ 323 (CCPA 1981).

No claim is allowed.

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Applicant's amendment necessitated the new ground of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Jeff Lundgren, can be reached 571-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 9, 2012

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1629